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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/776,786	05/01/1997	MARTINE BARKATS	ST94065-US	2477

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EXAMINER	
PRIEBE, SCOTT DAVID	
ART UNIT	PAPER NUMBER
1632	38

DATE MAILED: 06/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/776,786	Applicant(s) BARKATS ET AL.	
	Examiner Scott Priebe	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27,34-36,38,40,41 and 48-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27,34-36,38,40,41 and 48-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 4/17/02 has been entered.

Applicant's arguments filed 4/17/02 have been fully considered and the previous rejections are hereby withdrawn.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 27, 34, 35, 36, 38, 40, 41, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over French et al., US 6,290,949 (with priority to at least 9/1/93) in view of Mullenbach et al. UCLA Symp. Mol. Cell. Biol., New Ser., v. 82, pp. 313-326 (1988).

French et al. discloses a replication defective adenoviral vector (type 2 or type 5) comprising a coding sequence for glutathione peroxidase under control of CMV or RSV LTR

promoter. The adenoviral E1 region is deleted, and all coding sequence may be deleted. The vector is propagated in cultured mammalian cells, e.g. 293 cells, and used in gene therapy in treatment of cardiovascular disease, implicitly in humans. See entire document, e.g. col. 5, line 47; col. 7, lines 46-57; col. 8 line 8; col. 10; col. 12, lines 13-34 & 64-67. French et al. does not explicitly teach using a sequence encoding a human glutathione peroxidase.

However, Mullenbach et al. teaches the cDNA sequence human glutathione peroxidase (page 316-317, Fig. 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate cDNA encoding a human glutathione peroxidase, taught by Mullenbach et al., into the adenoviral vector (and cells) of French et al. since the patients of the therapy taught in French are primarily human, and using a gene encoding the human protein carries less risk of provoking an immune response against the glutathione peroxidase in humans than would the bovine protein, for example, which is not identical to the human protein.

Claims 27, 34-36, 38, 40, 41, and 48-50 are rejected under 35 U.S.C. 102(e)/103(a) as being unpatentable over Ohya et al., US 5,187,078, in view of McClelland et al., U.S. 5, 543,328.

Ohya et al. teaches generic plasmid and viral vectors comprising a gene encoding a human glutathione peroxidase for transfection of mammalian cells to be used for producing recombinant glutathione peroxidase in culture, such as for use as a pharmaceutical. See entire

document, for example col. 5, lines 38-51. Ohya et al. does not teach to make a replication deficient adenoviral vector for this purpose.

However, McClelland et al. disclose recombinant adenoviral vectors as gene delivery vehicles (col. 1, lines 4-5), e.g. based on Ad5 (see claim 5), that are defective in replication due to deletion of the E1 region and optionally parts of the E2 and E4 regions (col. 4, lines 13-28). It teaches that adenoviral vectors are advantageous for gene delivery due to their well-characterized genetics and stability (col. 1, lines 9-19). The vectors comprise DNA encoding a protein of interest, particularly of therapeutic interest, under control of the major late promoter (MLP), or CMV promoter (col. 3, lines 23-34). Cells which can be transfected include human cells and fibroblasts, myoblasts, endothelial cells, hepatocytes, keratinocytes, and brain and other neural cells (col. 5, lines 56 to col. 6, line 3). The reference teaches using such transfected cells in culture to produce a protein of interest or a therapeutic agent (col. 6, lines 58-62).

Therefore it would have been obvious to one of skill in the art to have made an adenoviral vector of McClelland et al. carrying the gene encoding the human glutathione peroxidase of Ohya et al. for transfecting cultured mammalian cells for production of the glutathione peroxidase since McClelland et al taught that the adenoviral vectors were useful for the purpose disclosed in Ohya et al. and were advantageous for such a purpose.

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX numbers are (703) 308-4242 or (703) 305-3014 for any type of communication. In addition, FAX numbers for a computer server system using RightFAX are

also available for communications before final rejection, (703) 872-9306, and for communications after final rejection, (703) 872-9307, which will generate a return receipt. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

Any inquiry concerning administrative, procedural or formal matters relating to this application should be directed to Patent Analyst Patsy Zimmerman whose telephone number is (703) 308-8338. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Scott D. Priebe

Scott D. Priebe, Ph.D.
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Technology Center 1600
Art Unit 1632